

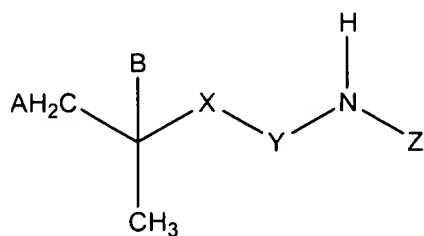
IN THE CLAIMS:

Claims 35, 37-42, 44-55, and 57 are proposed to be amended herein. Please note that all claims currently pending and under consideration in the above-referenced application are shown below. Please enter these claims as amended. This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claims 1-34 (Canceled)

35. (Currently amended) An oral sustained-release pharmaceutical composition comprising a core matrix comprising (1)-a therapeutically effective amount of an active compound and (2)-a gelling agent, wherein the amount of ~~said the~~ active compound represents from about 40-70% 40% to about 70% by weight of the oral-sustained release pharmaceutical composition, and wherein ~~said the~~ active compound is selected from the group consisting of: isovaleric acid, a pharmaceutically acceptable salt of isovaleric acid, a pharmaceutically acceptable ester of isovaleric acid, a compound having the structure:



wherein

- A = H, CH₃, or OH,
- B = H, OH, or CH₃,
- X = CH₂, CHCH₃, C(CH₃)₂, -O-, CH(OH), or -CH₂O-,
- Y = -CO-, or -SO₂-, and
- Z = H, CH₂CO₂H, or CH₂CONH₂,

and a compound selected from the group consisting of isovaleramide, 2-methylisovaleramide, 3-methylisovaleramide, 2,2-dimethylisovaleramide, 2,3-dimethylisovaleramide, 4-methylisovaleramide, 2,4-dimethylisovaleramide, 3,4-dimethylisovaleramide, 2,2,4-

trimethylisovaleramide, 3-hydroxyisovaleramide, 4-hydroxyisovaleramide, 4-hydroxy-3-methylisovaleramide, 2-hydroxyisovaleramide, N-(2-acetamido)isovaleramide, 2-methyl-1-propylsulfonamide, 1-methylethyl sulfamate, 2-methyl-1-propyl sulfamate, isopropyl carbamate, and isobutylcarbamate.

Claim 36 (Canceled)

37. (Currently amended) ~~A-~~ The oral sustained-release pharmaceutical composition according to claim 35, wherein ~~said the~~ the oral sustained-release pharmaceutical composition releases ~~said the~~ the active compound at a rate sufficient to maintain a therapeutically effective serum concentration of ~~said the~~ the active compound for at least 8 hours.

38. (Currently amended) ~~A-~~ The oral sustained-release pharmaceutical composition according to claim 35, wherein ~~said the~~ the oral sustained-release pharmaceutical composition releases ~~said the~~ the active compound at a rate sufficient to maintain a therapeutically effective serum concentration of ~~said the~~ the active compound for at least 12 hours.

39. (Currently amended) ~~A-~~ The oral sustained-release pharmaceutical composition according to claim 35, wherein ~~said the~~ the gelling agent comprises xanthan gum.

40. (Currently amended) ~~A-~~ The oral sustained-release pharmaceutical composition according to claim 35, wherein ~~said the~~ the oral sustained-release pharmaceutical composition has a film-coating that retards access of liquids to the active compound and/or retards release of the active compound through the film-coating.

41. (Currently amended) ~~A-~~ The oral sustained-release pharmaceutical composition according to claim 35, further comprising ~~one or more excipients~~ at least one excipient.

42. (Currently amended) ~~A-~~ The oral sustained-release pharmaceutical composition according to claim 35, wherein ~~said the~~ the active compound is isovaleramide.

Claim 43 (Canceled)

44. (Currently amended) ~~A~~ The oral sustained-release pharmaceutical composition according to claim 40, wherein ~~said film-coating the film-coating~~ comprises a polymeric coating material.

45. (Currently amended) ~~A~~ The oral sustained-release pharmaceutical composition according to claim 44, wherein ~~said the~~ polymeric coating material comprises a mixture of ethyl cellulose and hydroxypropyl methylcellulose.

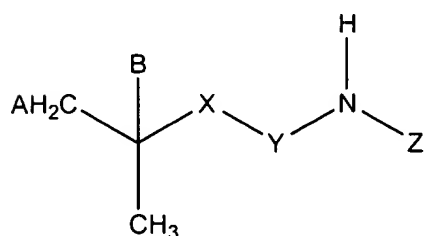
46. (Currently amended) ~~A~~ The oral sustained-release pharmaceutical composition according to claim 44, wherein ~~said the~~ polymeric coating material further comprises a plasticizer.

47. (Currently amended) ~~A~~ The oral sustained-release pharmaceutical composition according to claim 35, wherein the oral sustained-release pharmaceutical composition is in the form of a tablet, capsule, or multiparticulate composition.

48. (Currently amended) A process for preparing an oral sustained-release pharmaceutical composition comprising a core matrix comprising (1)-a therapeutically effective amount of an active ~~compound and~~ (2)-compound, a gelling agent, and (3)-optionally ~~one or more substances~~ at least one substance that further retards the release of the active compound, the method comprising:

- (a)-mixing together a therapeutically effective amount of an active compound with a gelling agent and optionally ~~one or more substances~~ at least one substance that further retards the release of the active compound, and
- (b)-compressing or extruding ~~said the~~ active compound, gelling agent, and at least one optional ~~substances~~ substance that ~~act~~ acts to sustain release of the active compound, wherein the amount of ~~said the~~ active compound represents from about 40-70% 40% to

about 70% by weight of the oral sustained-release pharmaceutical composition, and wherein the active compound is selected from the group consisting of: isovaleric acid, a pharmaceutically acceptable salt of isovaleric acid, a pharmaceutically acceptable ester of isovaleric acid, an active compound having the structure:



wherein A = H, CH₃, or OH,
 B = H, OH, or CH₃,
 X = CH₂, CHCH₃, C(CH₃)₂, -O-, CH(OH), or -CH₂O-,
 Y = -CO-, or -SO₂-, and
 Z = H, CH₂CO₂H, or CH₂CONH₂,

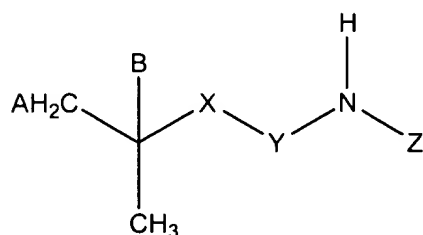
and a compound selected from the group consisting of isovaleramide, 2-methylisovaleramide, 3-methylisovaleramide, 2,2-dimethylisovaleramide, 2,3-dimethylisovaleramide, 4-methylisovaleramide, 2,4-dimethylisovaleramide, 3,4-dimethylisovaleramide, 2,2,4-trimethylisovaleramide, 3-hydroxyisovaleramide, 4-hydroxyisovaleramide, 4-hydroxy-3-methylisovaleramide, 2-hydroxyisovaleramide, N-(2-acetamido)isovaleramide, 2-methyl-1-propylsulfonamide, 1-methylethyl sulfamate, 2-methyl-1-propyl sulfamate, isopropyl carbamate, and isobutylcarbamate.

49. (Currently amended) ~~A~~ The process according to claim 48, wherein ~~said the~~ gelling agent comprises xanthan gum.

50. (Currently amended) ~~A~~ The process according to claim 48, further comprising ~~the~~ step of coating the core matrix with a polymer solution to form a film coating.

51. (Currently amended) A method of treating a pathology that is ameliorated by a modulation of CNS activity, wherein ~~said the~~ the pathology is selected from the group consisting of

convulsions, spasticity, affective mood disorder, neuropathic pain syndrome, headache, restlessness syndrome, movement ~~disorder~~ ~~substance abuse/craving disorder~~, substance abuse, craving, and cerebral trauma, comprising administering to a patient suffering from ~~said the~~ pathology an oral sustained-release pharmaceutical composition comprising a core matrix comprising (1) a therapeutically effective amount of an active compound and (2) a gelling agent, wherein the amount of ~~said the~~ active compound represents ~~from about 40-70%~~ 40% to about 70% by weight of the oral sustained-release pharmaceutical composition, and wherein ~~said the~~ active compound is selected from the group consisting of: isovaleric acid, a pharmaceutically acceptable salt of isovaleric acid, a pharmaceutically acceptable ester of isovaleric acid, isovaleramide, a active compound having the structure:



wherein A = H, CH₃, or OH,
 B = H, OH, or CH₃,
 X = CH₂, CHCH₃, C(CH₃)₂, -O-, CH(OH), or -CH₂O-,
 Y = -CO-, or -SO₂-, and
 Z = H, CH₂CO₂H, or CH₂CONH₂,

and a compound selected from the group consisting of 2-methylisovaleramide, 3-methylisovaleramide, 2,2-dimethylisovaleramide, 2,3-dimethylisovaleramide, 4-methylisovaleramide, 2,4-dimethylisovaleramide, 3,4-dimethylisovaleramide, 2,2,4-trimethylisovaleramide, 3-hydroxyisovaleramide, 4-hydroxyisovaleramide, 4-hydroxy-3-methylisovaleramide, 2-hydroxyisovaleramide, N-(2-acetamido)isovaleramide, 2-methyl-1-propyl sulfonamide, 1-methylethyl sulfamate, 2-methyl-1-propyl sulfamate, isopropyl carbamate, and isobutylcarbamate,

with the proviso that the treated pathology is not convulsions when the compound is 3-methylisovaleramide, isopropyl carbamate, or isobutyl carbamate.

52. (Currently amended) ~~A-The~~ method according to claim 51, wherein ~~said~~ the oral sustained-release pharmaceutical composition is in tablet form and the tablet contains a therapeutically effective unit dose of the active compound.

53. (Currently amended) ~~A-The~~ method according to claim 51, wherein ~~said~~ the oral sustained-release pharmaceutical composition is a multiparticulate composition and the multiparticulate composition contains a therapeutically effective unit dose of the active compound.

54. (Currently amended) ~~A-composition~~ The method according to claim 51, wherein ~~said~~ the gelling agent comprises xanthan gum.

55. (Currently amended) ~~A-The~~ method according to claim 51, wherein ~~said~~ the oral sustained-release pharmaceutical composition further comprises a film-coating comprising a polymeric coating material.

Claim 56 (Canceled)

57. (Currently amended) ~~A-The~~ method according to claim 51, wherein ~~said~~ the active compound is isovaleramide.

Claims 58 and 59 (Canceled)